

## **REMARKS/ARGUMENTS**

1. Applicants respectfully request reconsideration in view of the above amendments and the following remarks and arguments.
2. Claims 1-4, 8, and 23-25 are rejected under 35 U.S.C 102(a) as being anticipated by Rosiello (USPN 7,011,743), published as patent publication US 2003/0052065 (March 20, 2003), as set forth in the rejection of claims 1-4 , 8, and 23-25 in the office action of December 18, 2006. Claims 9-11, 13, and 16-17 are rejected under 35 U.S.C 102(b) as being anticipated by Dennehey et al. (USPN 5,482,440) as set forth in the rejection of claims 9-11, 13, and 16-17 in the office action of December 18, 2006. Claims 1, 9, 15-16 and 18-19 are rejected under 35 U.S.C 103(a) as being unpatentable over Rosiello in View of Dennehey as set forth in the rejection of claims 1, 9, 15-16 and 18-19 in the office action of December 12, 2006. Claims 5, 12, and 20 are rejected under 35 U.S.C 103(a) as being unpatentable over Rosiello in view of Dennehey as applied to claims 1, 9, and 16 and further in view of Grimm et al (USPN 6,245,570) as set forth in the rejection of claims 5, 12, and 20 in the office action of December 12, 2006. Claims 6, 7, 14, and 21-22 are rejected under 35 U.S.C 103(a) as being unpatentable over Rosiello in view of Dennehey as applied to claims 1, 9, and 16 and further in view of Juji et al. (USPN 5,098,371) as set forth in the rejection of claims 6, 7, 14, and 21-22 in the office action of December 12, 2006.
3. Applicants respectfully submit that the claimed invention is patentable over the cited references because, among other things, the cited references do not disclose or otherwise suggest a plurality of pump cassettes (i.e., each for use with a respective pump and each having a pump chamber and a fluid inlet in selective fluid communication with the pump chamber) connected by distribution tubing to a common inlet tube, as claimed. Claims 1, 9, 16, and 23 have been amended in view of certain comments made by the Examiner to clarify the relationships between various claim elements but are not substantively changed.

4. In comment 10(a), the Examiner disagreed with Applicants' argument that Rosiello's fluid management cassettes do not pump fluids and are not used with a plurality of pumps. Specifically, the Examiner argued that, in the embodiment shown in Figure 1, Rosiello teaches a pump 12 that pumps air and a peristaltic pump thus constituting a plurality of pumps being used with a plurality of cassettes. Further in response to Applicant's argument that the references fail to show certain features of Applicant's invention, the Examiner argued that the features upon which applicant relies (i.e., a one to one relationship between a cassette and a pump) are not recited in the rejected claim(s) and that the limitations as claimed do not include the limitation of a plurality of pump cassettes, each being in fluid communication with a separate pump.

Applicants respectfully submit that the claims do not merely require a plurality of pumps being used in conjunction with a plurality of cassettes, as suggested by the Examiner, but instead require a plurality of pumps "for use respectively with" the plurality of pumps.

In the context of the subject patent application, the "use" of a pump cassette with a pump involves the pump acting on the pump cassette, and specifically on a pump chamber of the pump cassette, to cause pumping of fluid. The "use" of a pump cassette with a pump does not merely involve an external pump that pumps fluid to or from a fluid management cassette, as in Rosiello. Thus, Applicants respectfully submit that Rosiello fails to include a plurality of pump cassettes for use with a plurality of pumps as claimed.

Furthermore, in the context of the subject patent application, the pump cassettes are for use "respectively" with the plurality of the pumps. Thus, each cassette is for use with a respective one of the pumps such that there is a one-to-one relationship between a cassette and a pump. Such an arrangement is discussed in the subject patent application, e.g., beginning at page 9, line 28 (with emphasis added):

Specifically, five pump cassettes, each connected to a RBCC container and an incubation bag for receiving the incubation solution, **are loaded respectively into the five blood pumps 104**. The five pump cassettes are preferably connected by a single working solution inlet tube to the

working solution container so that all five blood pumps draw working solution from the single working solution container. For convenience, the five interconnected pump cassettes along with their respective incubation bags and various plastic tubing may be referred to hereinafter as a "blood disposables set."

Thus, Applicants respectfully submit that Rosiello fails to disclose or suggest a plurality of pump cassettes for use respectively with the plurality of pumps as claimed.

5. In comment 10(a), the Examiner also argued that the recitation of "a first pump chamber" does not limit the claimed invention to having a plurality of pumps each having a pump chamber being in fluid communication with a separate cassette; rather, as claimed, the broadest interpretation yields the limitation of a plurality of cassettes, all in communication with a single pump chamber. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In Re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In the context of the subject patent application, it is the pump cassette, not the pump, that includes the pump chamber. The pump acts on the pump chamber of the cassette to accomplish pumping of the fluid. Such operation is discussed in the subject patent application, e.g., beginning at page 13, line 21:

A disposable pump cassette 202 is used to handle the various fluids. The pump cassette 202 serves as an interface between the blood pump 104, the RBCC container 106, and the incubation bag 118 so that no working solution, RBCC, or incubation solution comes into actual contact with the components of the blood pump 104. The blood pump 104 preferably uses pneumatics to operate the pump cassette 202 as well as other components, as discussed below. The blood pump 104 produces the incubation solution by causing working solution to be drawn into the working solution chamber 333 and pumping working solution from the

working solution chamber 333 into the channel 310 while drawing RBCC into the RBC chamber 334 through the channel 310.

Upon a review of the claim element “each cassette having a first fluid inlet port in selective fluid communication with a first pump chamber” in view of the Examiner’s comment, Applicants recognize that the wording may be ambiguous as to the location of the pump chamber, even though the detailed description makes it clear that the pump chamber is part of the pump cassette, not part of the pump that operates the pump cassette. Therefore, claim 1 is being amended to clarify that the pump cassette includes the pump chamber.

6. In comment 10(b), the Examiner disagreed with Applicants’ argument that Rosiello’s optical sensors are not pump chambers.

As discussed above, in the context of the subject patent application, a “pump chamber” is a component of a pump cassette that is operated upon by a pump to accomplishing pumping of fluid. Rosiello’s combination of optical sensor and manifold is not a “pump chamber” within the context of the subject patent application because it is not operated upon by a pump to accomplish the fluid pumping. Thus, Applicants respectfully submit that Rosiello does not include pump cassettes with pump chambers as claimed.

7. In comment 11(a), the Examiner argued that Dennehey’s cassettes are pump cassettes that include pump chambers. In fact, Dennehey’s cassettes are fluid management cassettes that include valve stations, pressure sensing stations, and channels or paths for conveying liquids (see Dennehey’s figs. 4-5 and supporting description at column 7, lines 41-46). Dennehey’s assembly includes a fluid path conveying blood between the source and the separation element. Several blood cassettes are located within the fluid path. However, nowhere does Dennehey teach or suggest that the blood cassettes have an inlet selectively coupled to a working solution pump chamber of the cassette as in the claimed invention. The Examiner suggests that elements F8 and F9 constitute working solution pump chambers. However, elements F8 and F9 are liquid

paths, not pump chambers as required by the claims. Specifically, elements F8 and F9 are described at column 9, lines 25-32 as a “liquid path” and a “primary liquid path,” respectively. While the larger diameters of liquid paths F8 and F9 relative to tube connectors T8 and T9 could arguably qualify them as “chambers” according to the description set forth in applicants’ amendment of April 18, 2007, it is clear that liquid paths F8 and F9 are not “pump chambers” within the context of the subject patent application because they do not perform pumping but instead are merely passages through which fluids pass within Dennehey’s cassette.

8. In comment 11(b), the Examiner argued that the umbilicus 24 constitutes a working solution inlet tube that joins the distribution tubing proximate to a junction between the distribution tubing and a middle one of the pump cassettes because it has a tubular structure and houses, via element 200, working solution-conveying tubing elements 42, 44 and 46.

In the context of the subject patent application, the inlet tube and distribution tubing provide a fluid path through which the plurality of pump cassettes can pump fluid from a common fluid source. The fact that Dennehey’s umbilicus is tubular in shape and conveys fluid does not make it an “inlet tube” in the context of the subject patent application. Rather, the umbilicus is simply a housing for the various lumen. As mentioned by the Examiner, different lumen are routed to different cassettes, but Dennehey does not appear to provide an inlet tube and distribution tubing that allows the pump chambers of the pump cassettes to be coupled to pump fluid from a common fluid source via the inlet tube and distribution tubing.

In addition, Dennehey also fails to teach the working solution inlet tube and distribution tubing configuration required by claim 9. Specifically, Dennehey does not teach or suggest a working solution inlet tube that joins distribution tubing proximate to a junction between the distribution tubing and a middle one of the pump cassettes. Claim 9 requires that a single working solution inlet tube (e.g., *a working solution inlet tube*) join the distribution tubing proximate to a junction between the distribution tubing and a middle of one of the pump cassettes. In contrast, the Dennehey system has essentially 5 separate working solution tubes leading to the cassettes. As best shown in Figure 19,

Dennehey has several tubing branches (38, 40, 42, 44, and 46) coming from a processing chamber (16) and leading to an umbilicus (24). Several additional sections of tubing (60, 76, 64, 86, and 80) extend from the umbilicus to the fluid cassettes (22A, B, and C). The Examiner suggests that the umbilicus (24) constitutes the working solution inlet tube. However, the umbilicus has a very distinct structure and cannot constitute the working solution inlet tube. The umbilicus includes 5 distinct lumens (e.g., flow paths) corresponding to each of the tubes entering and exiting the umbilicus (see Figure 16). At no point are the tubes a single working solution tube, as required by claim 9. Thus, nowhere does Dennehey teach or suggest the working solution tube/distribution tubing configuration required by claim 9.

Conclusion

For the reasons stated above, Applicants respectfully submit that all pending claims are in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicant respectfully requests early allowance of the application. The Applicant requests that the Examiner contact the undersigned, Jeffrey T. Klayman, if it will assist further examination of this application.

Applicants do not believe that any extension is required. In the event that an extension is needed, this conditional petition of extension is hereby submitted, and Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

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Respectfully submitted,

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